K110302

MAY 19 2011

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ..... 3M ESPE AG

Street: ..... ESPE Platz

ZIP-Code, City: ..... D-82229 Seefeld

Federal State: ..... Bavaria

Country: ..... Germany

Establishment Registration Number 9611385

Official Correspondent: ..... Dr. Desi W. Soegiarto,

..... Regulatory Affairs Specialist

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Date: ..... March 18, 2011

Name of Device

Proprietary Name: ..... Adhesive EXL 759

Classification Name: ..... Resin tooth bonding agent

Common Name: ..... Adhesive

Predicate Devices

Uno by 3M ESPE, Germany K071131

3M Dent System by 3M ESPE Dental Products, USA K962785

Scotchprime Ceramic Primer by 3M ESPE Dental Products, USA K853698

Description for the Premarket Notification

Adhesive EXL 759, manufactured by 3M ESPE, is classified as a Resin tooth bonding agent (21 C.F.R. §872.3200).
Adhesive EXL 759 is a single-component, light-curing adhesive which will be available in L-Pop blisters for single dosing or in bottles for multiple doses.
Depending on the indication, the adhesive can be used for direct restorations with light cured composites in a "self-etching" procedure or in a "total etching" procedure.
Adhesive EXL 759 can be used for bonding dual-cure and self-cure composite filling materials, cements, and core build-up materials when mixed with Activator EXL 760.

Predicate devices to which Adhesive EXL 759 has been compared are Uno (K071131, by 3M ESPE), 3M Dent System (K962785, by 3M ESPE), and Scotchprime Ceramic Primer (K853698, by 3M ESPE).

Adhesive EXL 759 is a one-component dental adhesive that is based on the chemistries of Uno (by 3M ESPE, Germany, K071131) and 3M Dent System (by 3M ESPE Dental Products, USA, K962785).

The intended use of Adhesive EXL 759 is comparable to the area of the intended use of the predicate devices of Adhesive EXL 759.

In this 510(k) premarket notification Adhesive EXL 759 has been compared to its predicate devices with regard to chemical composition, performance data, and indications for use. The comparison for chemistry, performance data, and indications for use shows that Adhesive EXL 759 is substantially equivalent to the predicate devices: Uno (K071131, by 3M ESPE), 3M Dent System (K962785, by 3M ESPE), and Scotchprime Ceramic Primer (K853698, by 3M ESPE).

The following tables show the performance data of Adhesive EXL 759 and its predicate device Uno and 3M Dent System, respectively:

Notched Edge Shear Bond Strength (Ultradent Method) [MPa]

	Adhesive EXL 759 self etch	
	enamel	dentin
Mean	26.4	35.8
Std. Dev.	2.5	2.7

	Uno self etch	
	enamel	dentin
Mean	25.3	33.66
Std. Dev.	2.2	3.2

	Adhesive EXL 759 total etch	
	enamel	dentin
Mean	32.4	31.8
Std. Dev.	5.1	4.1

	3M Dent System total etch	
	enamel	dentin
Mean	29.9	30.9
Std. Dev.	5.1	6.6

Knife Edge Shear Bond Strength with RelyX ARC (dark cure mode) [MPa]

Adhesive EXL 759 total etch / Activator EXL 760

	enamel	dentin
Mean	34.8	41.3
Std. Dev.	4.9	3.7

3M Dent System total etch

	enamel	dentin
Mean	33.7	37.0
Std. Dev.	8.2	7.1

Biocompatibility testing was carried out.

In summary, it can be concluded that Adhesive EXL 759 is as safe and effective as the predicate devices: Uno (K071131, by 3M ESPE), 3M Dent System (K962785, by 3M ESPE), and Scotchprime Ceramic Primer (K853698, by 3M ESPE).

Indications for Use:

- All classes of fillings (according to Black) with light-curing composite or compomer filling materials
- Cementation of indirect restorations (inlays, onlays, crowns, bridges, veneers) of composite, compomer, ceramic, and metal when combined with Suglue-10 Adhesive Resin Cement, manufactured by 3M ESPE
- Cementation of veneers when combined with RelyX Veneer Cement, manufactured by 3M ESPE
- Bonding of core build-ups made of light-curing composite or core build-up materials
- Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Activator EXL 760
- Repair of composite or compomer fillings
- Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
- Root surface desensitization
- Sealing of cavities prior to cementation of amalgamate restorations
- Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations
- Bonding of fissure sealants
- Protective varnish for glass ionomer fillings
- Surface treatment of porcelain, ceramics (including glass ceramics, zirconia and alumina), metal and composite.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Desi W. Soegiarto
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3M ESPE AG
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MAY 19 2011

Re: K110302
Trade/Device Name: Adhesive EXL 759
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: May 2, 2011
Received: May 6, 2011

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110302

INDICATIONS FOR USE

Device Name: Adhesive EXL 759

Indications for Use:

- All classes of fillings (according to Black) with light-curing composite or compomer filling materials
- Cementation of indirect restorations (inlays, onlays, crowns, bridges, veneers) of composite, compomer, ceramic, and metal when combined with Suglue-10 Adhesive Resin Cement, manufactured by 3M ESPE
- Cementation of veneers when combined with RelyX Veneer Cement, manufactured by 3M ESPE
- Bonding of core build-ups made of light-curing composite or core build-up materials
- Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Activator EXL 760
- Repair of composite or compomer fillings
- Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
- Root surface desensitization
- Sealing of cavities prior to cementation of amalgamate restorations
- Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations
- Bonding of fissure sealants
- Protective varnish for glass ionomer fillings
- Surface treatment of porcelain, ceramics (including glass ceramics, zirconia and alumina), metal and composite

(The official Statement of Indications for Use is provided on a separate form obtained from the FDA website.)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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